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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/630,074 | 07/30/2003 | David R. Milich | VACCINE-07971 | 9330 |

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| EXAMINER | |
|---|---|
| PENG, BO | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1648 | |

DATE MAILED: 06/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/630,074 | MILICH ET AL. | |
| | Examiner | Art Unit | |
| | Bo Peng | 1648 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *21 February 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *56-116* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *56-116* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/15/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

1. The examiner of your application in the Patent and Trademark Office has been changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Bo Peng, Art Unit 1648.

2. This Office Action is in response to the amendment filed 21 February 2006. Claims 1-55 are cancelled. Claims 56-116 are newly added; claims 56-116 are pending and are under consideration in this Office action.

### *Information Disclosure*

3. The PTO 1449 form mailed by Applicant on May 15, 2006 has been considered. The form has been initialed, signed and attached to this Office action.

4. The rejection of claims 25-54 under 35 U.S.C. §112, first paragraph, **is withdrawn** in view of the amendment.

5. The rejection of claims 25,27, 28, 30-33, 35-41, 43, 44 and 46-54 under 35 U.S.C. 102(b), as being anticipated by Birkett (US 6,231,864) **is withdrawn** in view of the amendment.

6. Following are new grounds of rejections necessitated by Applicant's amendment:

### *Claim Rejections - 35 USC § 112*

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 56-116 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession; at the time the invention was made, of the specific subject matter claimed. The courts have stated:

> "To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); *In re Gostelli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966." *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.* the court stated:

> "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other

> materials." *Fiers*, 984 F.2d at 1171, 25 USPQ2d 1601; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus ...") *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

MPEP § 2163 further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP § 2163 does state that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP § 2163. Although the MPEP does not define what constitute a sufficient number of representative species, the courts have indicated what do not constitute a representative number of species to adequately describe a broad generic. *In re Gostelli*, the courts determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872, F.2d at 1012, 10 USPQ2d at 1618.

The factors considered in the Written Description requirement are (1) *level of skill and knowledge in the art*, (2) *partial structure*, (3) *physical and/or chemical properties*, (4) *functional characteristics alone or coupled with a known or disclosed correlation between structure and function*, and the (5) *method of making the claimed invention*. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP § 2163.

9. In the instant case, claims 56-116 are drawn to a method of making a modified hepadnavirus core antigen by incorporating a heterologous antigen that has an isoelectric point below 7.0 into the said hepadnavirus core antigen. Because of no structural limitations (only cited biological property is an isoelectric point in the range of below 7.0) to the said heterologous antigens, no limitations to the insert sites in a hepadnavirus core, and no limitations to the species of hepadnaviruses, the scope of claims 1, 69 and 90 encompasses a method of making a modified hepadnavirus core antigens by incorporating any foreign peptides/proteins into any position of core proteins of any known and unknown hepadnaviruses.

10. As stated *supra*, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad genus. While having written description of a method of making a woodchuck hepatitis core antigens (WHcAg) by incorporating with foreign antigens less than 20-mer at the C-terminus of WHcAg identified in the specification tables and/or examples, the instant specification has not provided sufficient descriptive information about making modified hepadnavirus core antigens by incorporating any foreign peptides/proteins into any position of WHcAg, nor core antigens of other species of the hepadnaviruses, such as those from other rodents, avian, non-human primates, etc.

11. Consequently, while the skilled artisan would reasonably conclude Applicant was in possession of some modified WHcAgs incorporated with a few antigens at their C-terminus, there is no indication that Applicant was in possession of a method of making modified hepadnavirus core antigens of all species variant by incorporating any peptides/proteins into any positions of the core antigens as broadly claimed.

12. The description requirement of the patent statute requires a description of an invention,

not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

13. Claims 56-116 are further rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for making a modified recombinant WHcAg by incorporating a foreign antigen less than 20-mer into its C-terminus, does not reasonably provide enablement for a method of making all modified hepadnavirus core antigens by incorporating any peptides/proteins into any positions of any known or unknown species of hepadnavirus core antigens. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention without undue experimentation.

"[T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" *Genentech Inc. v. Novo Nordisk* 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997); In re Wright 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); See also *Amgen Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed. Cir. 1991); *In re Fisher* 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). Further, in *In re Wands* 858 F.2d

731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) the court stated:

> Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman [230 USPQ 546, 547 (BdPatAppInt 1986)]. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).

14. Claims 56-116 are drawn to a method of making a modified hepadnavirus core antigen by incorporating a heterologous antigen that has an isoelectric point below 7.0 into the any core antigens of hepadnaviruses.

15. As discussed *supra*, because of no structural limitations (the only cited biological property is an isoelectric point in the range of below 7.0) to the said heterologous antigens, no limitations to the insert sites in a hepadnavirus core, and no limitations to the species of hepadnaviruses, the scope of claims 1, 69 and 90 encompasses a method of making modified hepadnavirus core antigens of all species of hepadnaviruses by incorporating any foreign peptides/proteins into any position of the core antigens. However, the only working examples in the specification are directed to a method of making modified WHcAg incorporated with a few antigens of less than 20-mer at the C-terminus of the WHcAg. The instant specification has not provided sufficient descriptive information about incorporating any foreign peptides/proteins

into any positions of WHcAg, nor into all core antigens of other species variants of hepadnaviruses.

16. The state of the art at the time the application was filed recognized that heterologous human hepatitis core proteins (HBcAg) were capable of forming virus like particles (VLP) and can be used as carrier proteins to display foreign epitopes. However, "the size and nature of epitopes that can be inserted into VLPs, in particular into their immunodomainant regions, is restricted and VLPs containing peptides longer than 20 amino acids often fail to assemble (Jegerlehner 2002). Also, modifying the core antigen by inserting amino acids has an unpredictable effect on antigenicity and the carver proteins' ability to form particles. For example, changing the composition of a heterologous cytomegalovirus antigen/HBV nucleocapsid protein produced different results for VLP assembly and antigenicity (Tarar, M.R. FEMS (December 1996) 16, 183192. Moreover, it has been demonstrated by Koschel that deletions and insertions at random positions between M1 and E145 of HBcAg can affect the capsid formation. Of the 110 mutations, 38 allowed capsid formation (Koschel, J. Virology, 73 (1999), pp 2153-2160, cited on IDS). Since the species variants of core antigens differ in their sequence and structural requirement for their capsid formations, one skilled in the art would need specific directions on how to substitute and/or insert acidic amino acids that rescue the core antigen's antigenicity and ability to form particles. Making heterologous capsid proteins of hepadnavirses that are antigenic and capable of forming particles requires knowledge of the specific regions that can be modified. The specification, however, fails to provide these directions for other known and unknown species variants of core antigens. There is no discussion of the core regions of other viruses that would support the insertion of a heterologous antigen.

Based on the lack of direction and unpredictability discussed above, one skilled in the art would have to invest undue experimentation in order to make and use the claimed invention.

17. Since the structural limitations of the claims clearly cover a method of making a genus of modified hepadnavirus core antigens incorporated with any foreign peptides/proteins, in view of the empirical and unpredictable nature of the art, and lack of guidance and working examples with respect to appropriate modifications, one skilled in the art would have to do an **undue** amount of experimentation to identify suitable epitopes and insertion sites of species variants encompassed by the claims to practice the claimed invention. Therefore, the instant invention, based on the evidence as a whole, in light of the factors articulated by the court in *In re Wands*, lacks an enabling disclosure.

### *Claim Rejections - 35 USC § 102*

18. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

19. Claims 56-66, 68-83, 85-99 and 101-115 are rejected under 35 U.S.C. 102(b) as being anticipated by Pumpens (1995, cited on IDS as reference).

20. Claims 56-66, 68-83, 85-99 and 101-115 are drawn to a method of making a modified hepadnavirus core antigen by incorporating a heterologous antigen that has an isoelectric point between 3.0-5.0 into the said hepadnavirus core antigen, wherein said hepadnavirus core antigen

comprising an artificial C-terminus, wherein said adding acidic amino acid residue within immunodominant loop of said hepadnavirus core antigens, wherein said hepadnavirus core antigen is a human hepadnavirus core antigen.

21. Pumpens teaches the utility of hepatitis B virus core antigen particles as epitope carriers. In tables 1 through 3 of Pumpens a number of insertion sites are shown for heterologous antigens. These include N-terminal, C-terminal and internal insertions. Pumpens also discusses some potential sites for insertions on page 66, col. 1.

22. According to the MPEP, a species will anticipate a claim to a genus. "A generic claim cannot be allowed to an applicant if the prior art discloses a species falling within the claimed genus." The species in that case will anticipate the genus. *In re Slayter*, 276 F.2d 408, 411, 125 USPQ 345, 347 (CCPA 1960); *In re Gosteli*, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989) (Gosteli claimed a genus of 21 specific chemical species of bicyclic thia-aza compounds in Markush claims. The prior art reference applied against the claims disclosed two of the chemical species. The parties agreed that the prior art species would anticipate the claims unless applicant was entitled to his foreign priority date) (see MPEP 2131.02).

23. Since HBcAg is a species of hepanavirus, the method of making a recombinant HBsAg containing a foreign peptide as taught by Pumpens will anticipate a method of making a recombinant hepadnavirus core antigen (genus) according to the MPEP. It should be noted that isoelectric points are a biological property of amino acids. Pumpens discloses the epitopes incorporated in HBcAg particles through inherency. As shown in Table 17 of the instant specification, Applicant has demonstrated that positively charged inserts (e.g., pI equal to or greater than 7.0) appear to adversely effected assembly of hybrid WHcAg or HBcAg particles. In

other words, the recombinant HBcAg disclosed by Pumpens would have a property of isoelectric point less than 7.0 because they can form stable VPLs. Thus, the epitopes incorporated in HBcAg particles inherently have isoelectric points less than 7.0. Therefore, the method of making a recombinant HBsAg incorporating a foreign peptide as taught by Pumpens meets the limitation of instant claims 56-66, 68-83, 85-99 and 101-115, and anticipates the claimed invention.

***Claim Rejections - 35 USC § 103***

24. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

25. Claims 55-116 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pumpens, P. et al. (1995, cited on IDS) and Birkett (6,231,864).

26. Pumpens teaches the utility of hepatitis B virus core antigen particles as epitope carriers. Pumpens teaches that human hepatitis B virus core antigen shows strong conservation with hepatitis core antigen sequences from other species. (See page 64, col. 2) In tables 1 through 3 of Pumpens a number of insertion sites are shown for heterologous antigens. These include, N-terminal, C-terminal and internal insertions Pumpens also discusses some potential sites for insertions on page 66, col. 1.

27. Birkett teaches the similarity of WHcAg with HBcAg (column 10, paragraph 2 and SEQ ID NO:7).

28. One of ordinary skill in the art would have been motivated to produce recombinant WHcAg using the method of modifying HBcAg taught by Pumpens and Birkett. One would have a reasonable expectation of success because both Pumpens and Birkett teach that WHV core antigen has the strong similarity to the human counterpart and have inherent mutimerization capacity, such as particle-forming viral capsid, and the techniques involved were well-developed at the time of Applicant's invention. Absence any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in making recombinant WHcAg using the method of recombinant HBcAg taught by Pumpens and Birkett. Therefore the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

***Double Patenting***

29. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the

scope of a joint research agreement. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

30. Claims 56-116 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 25-30 of copending Application No. 10/630,070. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to a same process of making recombinant core antigens of hepadnaviruses.

31. The instant claims 56-116 are drawn to a method of making a modified hepadnavirus core antigen by incorporating a heterologous antigen that has an isoelectric point below 7.0 into the said hepadnavirus core antigen.

32. Claims 25-30 of copending Application No. 10/630,070 claim a method for producing an immunogenic composition, comprising expressing recombinant WHcAg containing heterologous antigen, heterologous antigen have an isoelectric point in the range 3.0 to 6.0.

33. Since the method of making recombinant WHcAg of copending Application 10/630,070 is a species of a hepadnavirus (genus) of the instant claims 56-116, the method of making recombinant WHcAg (species) of the co pending 10/630,070 will anticipate the method of making a recombinant hepadnavirus (genus).

***Remarks***

34. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bo Peng, Ph.D. whose telephone number is 571-272-5542. The examiner can normally be reached on M-F, 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, Ph. D. can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

BP

Bo Peng, Ph.D.

6/8/06

JEFFREY STUCKER
PRIMARY EXAMINER